REMARKS

Claims 1-46 were pending in this application. Claims 10, 17, 22, 23 and 27-46 are now cancelled without prejudice to Applicants' right to prosecute their subject matter in the present application and in related applications. New claim 47 is added and claims 1, 8, 9, 12, 15, 16, 24 and 26 are currently amended. Accordingly, claims 1-9, 11-16, 18-21, 24-26 and 47 are pending and presented for consideration.

Claim amendments

Support for the claim amendments can be found in the specification, including the claims as originally filed. Specifically, support for new claim 49 is found in the specification at least, for example, from page 5, line 26, to page 6, line 5. Support for the recitation of "the fusion protein lacks an immunoglobulin variable domain" in amended claims 1 and 15 is found in the specification at least, for example, at page 8, lines 25-28, and at page 20, lines 18 and 19. Support for the recitation of "whose ability to bind an Fc receptor is not modified by mutation" in amended claims 1 and 15 is found at least, for example, from page 20, line 27, to page 21, line 2. Support for the recitation of "Prostate-Specific Membrane Antigen" in amended claims 1 and 15 is found, for example, in Examples 1 and 3. Support for amending claim 15 to recite modes of administering the composition to the mammal is found at least, for example, from page 28, line 26, to page 29, line 9. Claims 8, 9, 12 and 26 have been amended to remove unnecessary language. Claims 16 and 24 have been amended for consistency with independent claim 15 from which they depend.

Applicants submit that these amendments introduce no new matter.

Telephonic interview

Applicants thank Dr. Canella for the telephonic interview on August 18, 2003, discussing the outstanding rejections in this patent application. Applicants have attempted to incorporate the substance of Dr. Canella's suggestions, provided in the Office action and during the

interview, into the present paper. The following comments address the claim objection and rejections in the order that they were raised in the Office action.

Claim Objection Under 37 C.F.R. 1.75 (c)

The Office action objects to claims 10, 17 and 22 under 37 C.F.R. 1.75(c). Applicants have canceled claims 10, 17 and 22. Accordingly, Applicants respectfully submit that the objection to claims 10, 17 and 22 under 37 C.F.R. 1.75(c) is moot.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 8-10, 15-26 and 44-46 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 10, 17, 22-23 and 44-46 have been cancelled without prejudice. The Office action alleged that claims 8, 9, and 26 were rendered indefinite by their recitations of "defining" or "corresponding to." Applicants have amended claims 8, 9, and 26 to adopt the Examiner's recommended wording. The Office action further alleged that claims 1, 10, 15 and 22 were rendered indefinite by their recitations of "a prostate specific membrane protein." Applicants have cancelled claims 10 and 22 and have amended claims 1 and 15 to recite "Prostate Specific Membrane Antigen," a specific, known protein. In view of the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 44 and 45 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly drawn to new matter. Applicants have cancelled claims 44 and 45 without prejudice, rendering the rejection moot.

All claims stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly violating the written description requirement by attempting to claim methods using a genus of prostate specific membrane antigens without adequate structural description of the antigens in the specification. Without acquiescing to the merits of the rejection, and solely to advance prosecution, Applicants have amended the independent claims in the Markush group of antigens to substitute "Prostate Specific Membrane Antigen," a known protein, for the genus of "prostate specific membrane

antigens." In view of the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 15 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling an antigen or adjuvant fusion protein linked by a disulfide bond to a second immunoglobulin heavy chain constant region. Without acquiescing to the merits of the rejection, and solely to advance prosecution, Applicants have cancelled claim 23. In view of the cancellation of claim 23, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. § 102

Heijnen *et al.*, Journal of Clinical Investigation, 1996, vol. 97, pp. 331-338 ("Heijnen")

Claim 46 stands under 35 U.S.C. § 102(b) as allegedly anticipated by Heijnen. Applicants have canceled claim 46. Therefore, Applicants respectfully submit that the rejection of claim 46 under 35 U.S.C. § 102(b) is moot.

U.S. Patent No. 6,086,875 ("Blumberg")

Claims 15-17 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Blumberg. Claim 17 has been cancelled. Applicants traverse the rejection of claims 15 and 16.

Applicants have amended claim 15 to recite a composition for eliciting an immune response against an antigen in a mammal, wherein the composition is administered to the mammal intramuscularly, intravenously, transdermally or subcutaneously. Blumberg does not teach a composition that is administered intramuscularly, intravenously, transdermally or subcutaneously. Accordingly, Applicants submit that Blumberg cannot anticipate claim 15 or any claim (*e.g.* 16) depending from claim 15.

Applicants respectfully request reconsideration and withdrawal of the rejection.

U.S. Patent No. 6,277,375 ("Ward")

Claim 46 stands rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Ward. Applicants have canceled claim 46. Therefore, Applicants respectfully submit that the rejection of claim 46 under 35 U.S.C. § 102(e) is moot.

Claim Rejections Under 35 U.S.C. § 103

Ward and Blumberg

Claims 44-46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ward in view of Blumberg. Applicants have canceled claims 44-46. Therefore, Applicants respectfully submit that the rejection of claims 44-46 under 35 U.S.C. § 103(a) is moot.

U.S. Patent No. 6,406,689 ("Falkenberg"); WO 95/31483 ("Cardy"); U.S. Patent No. 5,538,866 ("Israeli"); Liu *et al.*, (1998) Blood, 92:3730-3736 ("Liu"); and Roitt *et al.*, (1993) Immunology, p.84 ("Roitt")

Claims 1-3, 5-7, 10, 14, 15, 18-20, 22, 24, 25 and 46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Falkenberg in view of Cardy. Claims 1-3, 5-7, 10, 14, 15, 18-20, 22, 24-25 and 46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Falkenberg in view of Cardy and Israeli. Claims 1-3, 5-7, 10, 14, 15, 18-22, 24-25 and 46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Falkenberg and Cardy in further view of Liu and Roitt. Applicants have canceled claims 10, 22 and 46 without prejudice. Applicants respectfully traverse the rejections as applied to the pending claims.

As amended, the claims relate to methods and compositions with a fusion protein comprising an antigen linked to an immunoglobulin heavy chain constant region; the fusion protein lacks an immunoglobulin variable domain. Neither Falkenberg nor Cardy teaches or suggests the use of a protein comprising an immunoglobulin heavy chain constant region without an immunoglobulin variable domain. Falkenberg does not teach or suggest a fusion protein with a heavy chain constant region without an immunoglobulin variable domain. The deficiency of

Falkenberg is not remedied by the addition of Cardy. Cardy does not teach or suggest a fusion protein with a heavy chain constant region without an immunoglobulin variable domain.

Furthermore, there is no motivation to modify Cardy to use an immunoglobulin heavy chain constant region without an immunoglobulin variable domain. The chimaeric polypeptides of Cardy require a binding portion such as an antibody or an "effective portion" thereof retaining some degree of specific binding affinity (Cardy, Abstract and p.3). The effective portion may be, for example, an Fab, Fv, SCA or scFV fragment (Cardy, p.3), *i.e.*, fragments that include a variable domain to provide specific binding affinity. The variable domain permits the polypeptides of Cardy to target a eukaryotic cell surface component (Cardy, Abstract and p.3) using, for example, an anti-MHC-II antibody (Cardy, Example 1), an anti-MBr1 antibody (Cardy, Example 2), an anti-Lewis Y antibody (Cardy, Example 3), or an antibody with specificity for an MHC class II antigen or for a surface immunoglobulin (Cardy, Example 5). There is no motivation to omit the immunoglobulin variable domains from the polypeptides of Cardy, as the polypeptides would lose their required specific binding affinity. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01. Because modification of antibody proteins of Cardy to omit immunoglobulin variable domains would render them unsatisfactory for their intended purpose (specific binding affinity), Applicants submit that even in combination Falkenberg and Cardy cannot render the claimed invention obvious.

Applicants submit Israeli, Liu and Roitt similarly fail to provide a motivation to use an immunoglobulin heavy chain constant region without an immunoglobulin variable domain. Because the cited references fail to teach or suggest the use of an immunoglobulin heavy chain constant region without an immunoglobulin variable domain as in the antigen-linked fusion proteins and methods of the pending claims, Applicants respectfully submit that the references cannot render obvious the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Falkenberg; Cardy; U.S. Patent No. 5,709,859 ("Aruffo"); and Ward

Claims 1-7, 10-20, 22, 24, 25 and 44-46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Falkenberg and Cardy in view of Aruffo and Ward. Applicants have cancelled claims 10, 17, 22 and 44-46 without prejudice. Applicants respectfully traverse the rejection as applied to the pending claims.

As amended, the claims relate to methods and compositions with a fusion protein comprising an antigen linked to an immunoglobulin heavy chain constant region whose ability to bind an Fc receptor is not modified by mutation; the fusion protein lacks an immunoglobulin variable domain. Neither Falkenberg nor Cardy teaches or suggests a fusion protein with an immunoglobulin heavy chain constant region whose ability to bind an Fc receptor is not modified by mutation and without an immunoglobulin variable domain. Regardless of the teachings of Aruffo and Ward, Applicants submit that there can be no motivation or suggestion to modify the antibodies of Cardy to omit immunoglobulin variable domains, as this would defeat the purpose of the antibodies of Cardy. Accordingly, Applicants submit that even in combination, the cited references cannot render the claimed invention obvious.

More generally, like Falkenberg and Cardy, Aruffo and Ward provide no motivation to generate the claimed invention and no reasonable expectation of success in doing so. Ward teaches mutant proteins with altered binding to Fc receptors, providing increased serum half-life (Ward, Abstract and col. 2, line 29, to col. 3, line 14). Like Falkenberg and Cardy, Ward does not teach or suggest methods or compositions for eliciting an immune response using an immunoglobulin heavy chain constant region (without a variable domain) whose ability to bind an Fc receptor is not modified by mutation. Furthermore, Ward does not suggest that an antigen linked to such a constant region could be used to elicit a stronger immune response in the mammal than the antigen alone and does not provide a reasonable expectation of such a result. Similarly, Aruffo, which does not relate to eliciting an immune response, fails to teach or suggest methods or compositions for eliciting an immune response using an immunoglobulin heavy chain constant region (without a variable domain) whose ability to bind an Fc receptor is not modified by mutation; fails to teach or suggest that an antigen linked to such a constant region could be

used to elicit a stronger immune response in a mammal than the antigen alone; and fails to provide a reasonable expectation of such a result.

Accordingly, Applicants submit that the cited references do not render the claimed invention obvious and respectfully request reconsideration and withdrawal of the rejection.

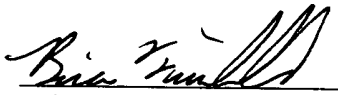
U.S. Patent No. 6,080,409 ("Laus")

Claim 45 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Laus. Applicants have cancelled claim 45 without prejudice and respectfully submit that the rejection of claim 45 is moot.

CONCLUSION

Claims 1-9, 11-16, 18-21, 24-26 and 47 are pending and presented for consideration. Dr. Canella is invited to telephone the undersigned agent to discuss any remaining issues.

Respectfully submitted,



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